



[3510-16]

DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

[Docket No.: PTO-P-2014-0028]

Grant of Interim Extension of the Term of U.S. Patent No. 5,686,060;

LUMASON™ (sulfur hexafluoride microbubble)

AGENCY: United States Patent and Trademark Office, Commerce.

ACTION: Notice of Interim Patent Term Extension.

SUMMARY: The United States Patent and Trademark Office has issued an order granting interim extension under 35 U.S.C. 156(d)(5) for a one-year interim extension of the term of U.S. Patent No. 5,686,060.

FOR FURTHER INFORMATION CONTACT: Mary C. Till by telephone at (571) 272-7755; by mail marked to her attention and addressed to the Commissioner for Patents, Mail Stop Hatch-Waxman PTE, P.O. Box 1450, Alexandria, VA 22313-1450; by fax marked to her attention at (571) 273-7755; or by e-mail to Mary.Till@uspto.gov.

SUPPLEMENTARY INFORMATION: Section 156 of Title 35, United States Code, generally provides that the term of a patent may be extended for a period of up to five years if the patent claims a product, or a method of making or using a product, that has been subject to certain defined regulatory review, and that the patent may be extended for interim periods of up to one year if the regulatory review is anticipated to extend beyond the expiration date of the patent.

On May 13, 2014, Bracco Suisse SA, the patent owner of record, timely filed an application under 35 U.S.C. § 156(d)(5) for an interim extension of the term of U.S. Patent No. 5,686,060. The patent claims the human drug product LUMASON™, sulfur hexafluoride microbubbles. The application indicates that Bracco Diagnostics Inc., an affiliate of patent owner Bracco Suisse SA, initially submitted a New Drug Application (NDA) # 21-315 to the Food and Drug Administration (FDA) on January 21, 2001, and withdrew NDA #21-315 on December 20, 2007. Bracco Diagnostics Inc. submitted a new NDA #203-684 on December 20, 2011. FDA accepted NDA 203-684 for filing on February 19, 2012.

Review of the application indicates that, except for permission to market or use the product commercially, the subject patent would be eligible for an extension of the patent term under 35 U.S.C. 156, and that the patent should be extended for one year as required by 35 U.S.C. 156(d)(5)(B). Because the regulatory review period will continue beyond the original expiration date of the patent, November 11, 2014, interim extension of the patent term under 35 U.S.C. 156(d)(5) is appropriate.

An interim extension under 35 U.S.C. 156(d)(5) of the term of U.S. Patent No. 5,686,060 is granted for a period of one year from the original expiration date of the patent.

August 26, 2014
Date

Andrew Hirshfeld
Deputy Commissioner for Patent Examination Policy
United States Patent and Trademark Office

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